

Please amend the application as follows:

In the specification:

At the top of page 1, replace the present cross-reference, following the heading CROSS-REFERENCE TO RELATED APPLICATIONS, with the new cross-reference below.

C 1 This application is a ~~divisional~~ continuation of application serial number 09/094,402 filed on June 10, 1998 (now U.S. Patent No. 6,117,165).

Replace the paragraph on page 2, lines 5-15 with the new paragraph below.

C 2 A common procedure for implanting a balloon-expandable stent in a blood vessel involves mounting the stent in its unexpanded, crimped state on a balloon-tip catheter of a suitable delivery system. The catheter is then slipped through an incision in the vessel wall and down the length of the vessel until it is positioned to bridge the diseased or narrowed portion of the vessel. The stent is then expanded with the aid of the balloon-catheter against the internal wall of the vessel. This may be done after the vessel has been ~~predilated~~ predilated and it has been determined that a stent is necessary. Alternatively the vessel could be dilated by the stent itself while the latter is

C2  
Concl expanded by means of the balloon. In both cases the stent will maintain its deployed, expanded form once the balloon is evacuated and the catheter retracted again in order to provide a permanent support for the blood vessel concerned.

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Replace the paragraph on page 4, lines 21-30 with the new paragraph below.

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C3 A specific embodiment of the endoprosthesis according to the invention is characterized in that said structure comprises a continuous filament which is separated from a tube wall, in that said adjacent undulations are staggered in a substantially helical configuration advancing along a longitudinal axis of the tubular body to form one of said at least one substantially helical pattern within said structure, and in that a first helical turn of said filament around said longitudinal axis of said tubular member is connected to an adjacent second such turn of said filament by means of at least one of said connection elements, being an integral extension of said filament. This embodiment to a large ~~extent~~ extent compares to the Cordis Coronary Stent referred to above, without however sharing the above described drawbacks of that device.

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Replace the paragraph on page 5, lines 12-29 with the new paragraph below.

C4  
In a preferred embodiment an endoprosthesis is according to the invention characterized in that said structure comprises a number of turns of said filament whereby the connection elements to subsequent turns are radially shifted to form at least one further substantially helical pattern of said at least one substantial helical pattern within said structure. In this manner a kind of primary framework structure may be obtained which supports the vessel wall while maintaining deployed flexibility. More specifically a preferred embodiment of the ~~endoprostheses~~ endoprosthesis according to the invention is ~~characterized~~ characterized in that at least a portion of the structure comprises a number of connection elements which are substantially equally divided in each turn of said filament and in that connection elements in successive turns are helically shifted by approximately one undulation pitch distance. By shifting the connection elements substantially a full pitch distance a structure is realized in which successive connection elements are linked to each other by substantially a full undulation of said first pattern. This undulation introduces significant slack and expandable diameter within the helical spine created by the interlinked connection elements which

C4  
Cancel  
allows a very gradual expansion of the device ~~transverse~~  
transverse to its longitudinal direction. This reduces so-  
called foreshortening which is a longitudinal shrinking of the  
device as it is expanded and would otherwise limit the effective  
range of the device.

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Replace the paragraph on page 6, lines 1-10 with the new  
paragraph below.

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C5  
A further specific embodiment of the device according to the  
invention is characterized in that at least some of the  
connection elements comprise a strut diagonally interconnecting  
a first side of a first adjoining undulation to an opposite side  
of a second adjoining undulation, the strut being entirely  
integral with said adjoining undulations and having a direction  
different to the helical direction of said one substantial  
helical pattern within said structure. Upon deployment, this  
structure, will create a kind of spine which runs over a series  
of connection elements in a different, or even contra-, helical  
direction compared to that of said one substantially helical  
pattern. Such multiple-helix structure is capable of  
~~withstanding~~ providing a significant hoop strength whilst still  
being flexible and conformal to the natural vessel wall.

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Replace the paragraph running from page 8, line 24 through page 9, line 5 with the new paragraph below.

Besides, or even instead of, being formed by a series of substantially helically staggered undulations, a substantially helically advancing pattern within the structure may also be created by the connection elements in themselves. In this respect, a specific embodiment of the endoprosthesis according to the invention is characterized in that said structure comprises at least one series of connection elements ~~with~~ which are substantially regularly distributed over at least part of the length of said tubular body and in that successive connection elements within said at least one series are radially shifted to form one substantially helical pattern within said structure. More specifically, a preferred ~~embodiments~~ embodiment of the endoprosthesis according to the invention is characterized in that said successive connection elements are mutually connected by an elongated member which has a greater length than the linear distance between said connection elements in said first unexpanded state of the structure, in order to impart radial expandability to the structure.

Replace the paragraph running from page 10, line 23 through page 11 line 7 with the new paragraph below.

C7 A still further embodiment of the endoprosthesis according to the invention is characterized in that said central portion of the tubular body comprises a first number of connection elements per full helical turn of said at least one substantially helical pattern within said structure, in that at least one of said intermediate portions comprises a second number of connection elements of the structure per full helical turn of said at least one substantially helical pattern within said structure, and in that the first number of connection elements is smaller than said second number of connection elements imparting a difference in flexibility between both portions of the tubular body. More precisely, the central portion will exhibit more flexibility than the intermediate portions due to the lower number of interconnections between adjacent turns. To accommodate this difference within the structure, a specific embodiment of the endoprosthesis according to the invention is characterized in that the central portion and ~~anyone~~ any one of said intermediate portions are separated from each other by a transitional portion in order to smoothly change the number of interconnections between adjacent turns from the first number to the second number of connection elements per full helical turn of said pattern.

Replace the paragraph on page 11, lines 9-25 with the new paragraph below.

C8 In a more specific embodiment the endoprosthesis according to the invention is characterized in that adjacent turns in said central portion comprise a number of connection elements which are equally divided and in that connection elements in subsequent turns are helically shifted by approximately one undulation pitch distance. For example, there could be six adjoining helical segments with three equally spaced connection elements, situated approximately 120° with respect to one another or six opposing helical segments with two equally spaced connection elements situated approximately 180° with respect to one another. This specific design yields the most flexible structure in the central region, both crimped and deployed. Once deployed, the structure will orient itself in line with the helical lattice structure which it forms, exhibiting three intertwining continuous lattice legs within the intermediate region and only two of those legs in the central region. The intermediate region will possess more stiffness in order to counteract the balloon expansion, known as the "dog bone effect", which causes the ends of the device to flare prematurely prior to the deployment of the central section and which results in an ~~unde~~ undue amount of foreshortening upon

C8  
Cand expansion. Moreover the intermediate regions serve as a relief between the end portions and the central region of the device.

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Replace the paragraph on page 13, lines 1 to 26 with the new paragraph below.

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C9  
The wall of the stent comprises a substantially continuous structure which in this example consists of a continuous filament which has been cut out from the tube wall in a substantially helical fashion with a width between about ~~0.10~~ 0.10 and ~~0.17~~ 0.17 mm. This may be done by means of laser cutting, electrochemical etching, electromechanical discharge or any other suitable technique preferably followed by a suitable surface treatment, like etching to deburr and or round off possible sharp edges. In this example a tubular body with an internal diameter of about 3.0 mm, a wall thickness of about 1.0 mm and a length of about 30 mm has been chosen as a starting material. However, other dimensions are likewise feasible within the scope of the present invention. Particularly the length may be adapted to the diseased part of the lumen to be stented in order to avoid the necessity of separate stents to cover the total area. The filament-structure comprises a number of undulations 2 which are mutually staggered in helical pattern advancing around a central longitudinal axis of the device. In



C9  
Cand

order to retain a coherent body subsequent turns 2A-2H of the filament are interconnected by means of one or more connection elements 31,32 which are entirely integral with the undulations thereby connected, as they are cut altogether from one and the same tubular body. To retain flexibility, both unexpanded as well as deployed, the number of connection elements per helical turn is less than the number of undulations in said turn. This is further elucidated in figure 2 which gives plan view of the device as if it were cut open. As emerges quite clearly from this figure, the connection elements 31 to subsequent turns are radially shifted by about half undulation pitch distance  $\frac{1}{2}L$  to form a helical pattern X-X, Y-Y. Once deployed, these patterns will expand to a helically turning spines which form a primary framework or scaffolding lattice of the deployed stent. This framework supports the vessel wall highly uniformly throughout the device and moreover is capable of withstanding substantial inwardly directed radial forces, ~~which~~. This capability of the framework is referred to as its hoop strength.

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Replace the paragraph running from page 13, line 28 through page 14, line 11 with the new paragraph below.

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C10

The lower drawing part of figure 2 shows a part of a central modular portion of the device in which successive turns of the

C10  
Cand  
filament are interconnected by means of only two connection elements 31, which are shifted about 180° with respect to one another, while the upper part shows an end portion of the device together with an intermediate portion in which three equally spaced connection elements 31,32 interconnect adjacent undulations from successive turns of the filament with each other. As a result the parent scaffolding lattice of the deployed device will be composed of only one helically advancing ~~spline~~ spline within the central region and will comprise two helically revolving spines within the other regions. Although the latter provides less flexibility, it leads to an improved adhesion to the balloon-catheter by which the device is guided through the lumen and moreover counteracts a so-called dog bone effect, which is a premature expansion at the tail ends of the device. The central portion of the device, i.e. the lower drawing part, on the other hand retains maximum flexibility and conformability due to the smaller number of interconnections between adjacent undulations within this segment.

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Replace the paragraph running from page 14, line 13 through page 15, line 2 with the new paragraph below.

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C11  
In this example two kinds of connection element are used, denoted 31 and 32 respectively. Both types of connection

elements feature a strut 3 which is S-shaped and diagonally interconnects opposite sides of adjacent undulations from successive turns of the filament in a helical direction different to that of the staggered undulations themselves, see also figure 3E. These struts will be referred to as major struts as they are part of the lattice spines described hereinbefore. The struts will be referred to as major struts as <sup>they</sup> ~~the~~ are part of the lattice spines described hereinbefore. The second type of interconnection element 32 moreover features a second, S-shaped diagonal 4 strut intersecting the first one, see also figure 3D. Due to this shape an interconnection element of the second kind 32 will first start to rotate around its central axis once the stent is being deployed with only a limited force being exerted axially in the diagonal 3 of the connection element. Only after the first diagonal 3 has become fully in line with the sides of the undulations it interconnects, does it ~~has~~ have to withstand the entire force axially. This incorporated slack and stress relief allows thinner strut width and filament width over the lattice legs which can be useful for decreasing the radio-opacity at this area as well as improves its unexpanded, crimped as well as deployed, expanded flexibility. Moreover the support area covered by a connection elements of this second kind will not decrease much upon deployment of the device. As a result a

C11  
Cand larger "scaffolding footprint" will remain after deployment compared to any of the other types of connection elements shown which all will stretch substantially upon deployment leaving only the thin major strut 3 as "scaffolding footprint".

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Replace the paragraph running from page 16, line 25 through page 17, line 2 with the new paragraph below.

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C12 A second embodiment of the device according to the invention is depicted in figures 5-7. This device comprises a tubular body 1 and has been manufactured using similar techniques as in the first embodiment, although in this case a more complicated structure has been created consisting of more than just a single, wrapped filament. However, like in the first embodiment, the structure of the device is composed of a substantially helical pattern of mutually staggered undulations 2, with connection elements 33 ~~interconnection~~ interconnecting some undulations from successive turns of said pattern. The connection elements within this structure primarily comprise two intersecting struts like the type reflected in figure 3D.

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Replace the paragraph on page 18, lines 15-20 with the new paragraph below.

C13 Likewise, the filament width as well undulation shapes may be varied and adapted to suit specific required characteristics besides the flexibility and stent-to-vessel ratio. For instance, the foreshortening of the device, i.e. the amount of length reduction upon expansion from the crimped to the deployed state of the device, its degree of recoil, its hoop strength as well as its radio-opacity may be so varied and adapted. In any event the present invention provides the designer with the greatest amount of freedom conceivable.

Replace the paragraph on page 18, lines 22-27 with the new paragraph below.

C14 Also the elongated members interlinking a series of connections elements like in the second embodiment need not coincide with undulations of the pattern and can be introduced in the structure as separate elements. These members moreover need not ~~necessarrily~~ necessarily comprise a full S-curved bent or even ~~no~~ any S-curved bent at all and may on the other hand consist of more than just one such bent. Also in this respect the designer has total freedom to tailor the device to his demands.